

# EXHIBIT D





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October 27, 2020

**VIA ELECTRONIC FILING**

The Honorable Jennifer L. Hall  
United States Magistrate Judge  
J. Caleb Boggs Federal Building  
844 N. King Street  
Wilmington, DE 19801

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC-JLH

Dear Magistrate Judge Hall:

I write in support of Defendant Eagle's request (D.I. 207) to: (1) strike Plaintiffs' expert Dr. Kirsch's report(s) raising untimely infringement theories, or allow Eagle's expert Dr. Park to respond; (2) supplement Eagle's invalidity expert reports to address Par's late-produced prior art sales records, and new infringement theories; and (3) take a supplemental deposition of Dr. Kirsch.

**Background:** Par alleges Eagle's proposed generic vasopressin product will infringe three patents claiming vasopressin compositions and their use to treat hypotension. Vasopressin has been used to treat hypotension for decades. Par's predecessor JHP sold an unapproved vasopressin product, "Pitressin," for years before the patents-in-suit. Many other companies sold unapproved vasopressin as well. But early last decade, the FDA began encouraging NDA filings for unapproved drugs, offering to remove competing formulations from the market in return for these filings. In September 2012, JHP [REDACTED] The FDA approved the NDA in 2014, and Par launched "Vasotrist." The FDA then removed all other vasopressin products from the market, [REDACTED] Both Pitressin and original Vasotrist are prior art to the patents-in-suit and so can be used to invalidate them.

Several years later, Eagle's joint venture partner began developing a generic version of original Vasotrist. [REDACTED] no patent-in-suit had issued and the lone published application had claims with no pH limitation. The patents arise from the purported discovery that increasing the pH from the [REDACTED] of prior art Pitressin and original Vasotrist, to pH 3.7–3.9, improves stability. Par alleges a *reformulated* Vasotrist (pH 3.8), launched in 2017, embodies the patents, while [REDACTED] do not. This creates several problems for Par: First, [REDACTED] Second, Par's recent, late-produced records show that [REDACTED]

In his opening infringement report, for the pH limitations, Par's expert Dr. Kirsch relied on [REDACTED] Eagle's expert Dr. Park responded that [REDACTED]

[REDACTED] Ex. 2, ¶¶ 94, 146–157. In reply, Dr. Kirsch challenged [REDACTED] but again ignored [REDACTED]. Ex. 3, ¶¶ 32–38. Expert discovery closed in February 2020. The May 2020 trial was later continued due to the pandemic.

***Par's Untimely Infringement Theories:*** As agreed, Eagle continued to produce pH data generated during the batches' shelf-life, and, on May 5, submitted a two-paragraph Park report confirming [REDACTED]. Ex. 4. Faced with these data, on May 8, [REDACTED]

[REDACTED] Ex. 5. Attempting to avoid dispute, Eagle initially did not object and instead Dr. Park responded to the new theory on June 8. Ex. 6. Par did not object. But on July 16, [REDACTED] data. Ex. 7. Eagle objected to yet another new theory, Ex. 8, but proposed a compromise: Eagle would not object if [REDACTED]

[REDACTED] Ex. 10.

***Par's Untimely Invalidity Production:*** On August 3, with the question of a further deposition still open, out of the blue and over 9 months after the close of fact discovery, [REDACTED] Ex. 14. During discovery, [REDACTED]. Eagle's experts had identified a number of batches having a pH in the claimed range, including [REDACTED]. Ex. 11, ¶¶ 119–30; Ex. 12, ¶¶ 150–55. But Par denied that [REDACTED] Ex. 13, ¶¶ 111–12. Thus, Eagle's experts focused on [REDACTED] Ex. 11, ¶¶ 127–29. Par's August 3 production shows that [REDACTED] Ex. 15; D.I. 204. Importantly, [REDACTED]

[REDACTED] Ex. 13, ¶¶ 108–10. But Par objected to Eagle serving supplemental reports addressing [REDACTED]. Ex. 15.

***Supplemental Reports:*** On September 16, Eagle's Dr. Park responded to [REDACTED], and its experts Park and Chyall addressing [REDACTED] Exs. 16–19. Par objected, stating that the May 8 Kirsch report should be the last permitted on infringement, while not addressing invalidity at all. Ex. 20. After another meet-and-confer, Eagle filed this motion. Par refused to seek leave for the May 8 or July 16 Kirsch reports, and declined to join Eagle's motion. Ex. 21. Par is not seeking to strike Eagle's supplemental reports. For the Court's convenience, a timeline of events is in Appendix A.

**Argument:** After expert discovery closed, “[n]o other expert reports [were] permitted without either the consent of all parties or leave of the Court.” D.I. 20, ¶ 11.a. “Good cause” to modify the schedule for supplemental expert reports “is present when the schedule [could not] be met despite the moving party’s diligence.” *Meda Pharm. Inc. v. Teva Pharm. USA, Inc.*, 2016 WL 6693113, at \*1 (D. Del. Nov. 14, 2016); Fed. R. Civ. P. 16(b)(4). Courts also consider the *Pennypack* factors, *i.e.*: (1) prejudice to the other party; (2) ability to cure any prejudice; (3) potential to disrupt orderly and efficient trial; (4) presence of bad faith by the disclosing party; and (5) importance of the evidence. *See Acceleration Bay LLC v. Activision Blizzard Inc.*, 2019 WL

4194060, at \*2 (D. Del. Sept. 4, 2019). Under these standards, Eagle's requests should be granted.

Regarding infringement, Eagle never consented to Dr. Kirsch's May 8 report—[REDACTED]—without Dr. Park having an opportunity to respond. And Par refused to seek leave for it. Without consent or leave, the May 8 Kirsch report is impermissible and should be stricken. And once that report is stricken, there is no need to consider permissibility of the June 8 and September 16 Park, and July 16 Kirsch, reports that followed.

If the May 8 Kirsch report is permitted, Eagle should be allowed "to submit a supplemental expert report to reply to Dr. [Kirsch's] newly disclosed opinions." *Vectura Ltd. v. GlaxoSmithKline, LLC*, 2019 WL 1436296, at \*2–3 (D. Del. Apr. 1, 2019). Par never objected to the responsive June 8 Park report. And Dr. Park obviously could not have responded earlier to a theory Par and Dr. Kirsch never disclosed. The *Pennypack* factors support Eagle too. Par cannot claim prejudice or bad faith when its own late-disclosed theories and lack of diligence created the need for the Park report. And Dr. Park's report is important to Eagle's case and will *promote* an orderly and efficient trial, as it will allow Eagle to respond to Dr. Kirsch's new theories at trial. Par's contention that it should be permitted to inject [REDACTED] into the case without response defies logic.

If the May 8 Kirsch report is admitted, then admitting the June 8 Park report should be the end of it. But Par did not stop there, instead submitting the July 16 Kirsch report raising [REDACTED] that could have been raised during expert discovery, and no later than the May 8 report. Eagle objected. Ex. 8. Par would not agree to Eagle's compromises, and declined to request leave for the report. Exs. 10, 20, 21. Absent consent or leave, the report should not be permitted. D.I. 20, ¶ 11.a. If it is, however, Dr. Park's September 16 response also should be allowed for the same reasons discussed above. Ex. 17. Indeed, Par already agreed. Exs. 10, 20. Finally, to the extent Dr. Kirsch is permitted to testify to one or both new theories, Eagle should in fairness be permitted to take a limited, supplemental deposition on them. *See Vectura*, 2019 WL 1436296, at \*2–3 (permitting supplemental deposition on expert's new opinions).

Regarding invalidity, good cause also exists for Eagle's supplemental invalidity reports. Had Par timely produced [REDACTED] Eagle's experts could have addressed them earlier. Par cannot rely on its own discovery failures to deny Eagle these strong invalidity positions. Par has not identified anything objectionable in the supplemental reports in any event. Ex. 20. Again, *Pennypack* supports Eagle. Par cannot claim prejudice or bad faith when the need for the reports is based on its own discovery failures. Eagle's discovery requests specifically sought [REDACTED]. Ex. 22. Par was obliged to search for and produce responsive documents. Yet it took Par until August of this year—about 10 months after the close of fact discovery, and three months after trial was to have taken place—for Par to finally do so. Thus, if anything, it is *Par* that acted in bad faith through late disclosures.

The supplemental opinions will not disrupt trial as they merely apply the experts' existing theories to the new evidence. Finally, the supplemental opinions are important to Eagle. [REDACTED]

And Eagle's experts should be allowed to take [REDACTED] into account on validity, where "[i]t is axiomatic that claims are construed the same way for both invalidity and infringement." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003).

The Honorable Jennifer L. Hall

October 27, 2020

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Respectfully,

*/s/ Bindu A. Palapura*

Bindu A. Palapura

BAP:nmt/6914232/45185

Enclosures

cc: Counsel of Record (via electronic mail)

**APPENDIX A**

<b>Date</b>	<b>Key Events</b>
Feb. 2020	Close of expert discovery
5/2/2020	Park supplemental report presenting new data
5/8/2020	Kirsch supplemental infringement report
6/8/2020	Park supplemental responsive non-infringement report
7/16/2020	Kirsch supplemental reply infringement report
7/29/2020	Eagle objects to Kirsch supplemental reply infringement report
8/3/2020	Par produces [REDACTED]
8/20/2020	First meet-and-confer
9/16/2020	Park supplemental sur-reply non-infringement report
	Park and Chyall supplemental invalidity reports
9/24/2020	Par objects to service of supplemental reports
10/13/2020	Second meet-and-confer
10/21/2020	Eagle files motion for a discovery teleconference

# EXHIBIT E

# EXHIBIT 1

**THIS EXHIBIT HAS BEEN  
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# EXHIBIT 2

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# EXHIBIT 3

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# EXHIBIT 5

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# **EXHIBIT 20**

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# **EXHIBIT 21**

**From:** [Michael J. Farnan](#)  
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**Cc:** [\\*dmoore@Potteranderson.com1](mailto:*dmoore@Potteranderson.com1)  
**Subject:** RE: [EXT] Activity in Case 1:18-cv-00823-CFC-JLH Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc. Order  
**Date:** Tuesday, October 20, 2020 5:13:17 PM  
**Attachments:** [Ltr to J. Hall re motion for discovery teleconference.DOCX](#)

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Bindu,

On the second bullet point, if Eagle wishes to raise this issue, Eagle can restore it as a request from Eagle rather than a joint request. Thank you

Michael

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**From:** Palapura, Bindu A. <[bpalapura@potteranderson.com](mailto:bpalapura@potteranderson.com)>  
**Sent:** Monday, October 19, 2020 5:03 PM  
**To:** Michael J. Farnan <[mfarnan@farnanlaw.com](mailto:mfarnan@farnanlaw.com)>; Brian Farnan <[bfarnan@farnanlaw.com](mailto:bfarnan@farnanlaw.com)>  
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**Subject:** FW: [EXT] Activity in Case 1:18-cv-00823-CFC-JLH Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc. Order

Michael/Brian: Attached is a letter pursuant to the order below. We've included our availability for a call next week. Note that there is a preference for after 3:30pm because one of our team members is overseas. However, we can be flexible if needed on the days listed.

Please let us know what works best for your team. We would like to get this on file tomorrow.  
Thanks.



**Bindu A. Palapura | Partner**

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**Sent:** Thursday, October 15, 2020 3:44 PM

**To:** [ded\\_ecf@ded.uscourts.gov](mailto:ded_ecf@ded.uscourts.gov)

**Subject:** [EXT] Activity in Case 1:18-cv-00823-CFC-JLH Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc. Order

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**U.S. District Court**

**District of Delaware**

## **Notice of Electronic Filing**

The following transaction was entered on 10/15/2020 at 3:44 PM EDT and filed on 10/15/2020

**Case Name:** Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc.

**Case Number:** [1:18-cv-00823-CFC-JLH](https://ecf.ded.uscourts.gov/caselist/1:18-cv-00823-CFC-JLH)

**Filer:**

**Document Number:** 206(No document attached)

### **Docket Text:**

**ORAL ORDER:** Having been advised that the parties are unable to resolve a discovery matter, they are directed to file a Motion for Teleconference to Resolve Discovery Dispute. The suggested text for this motion can be found in Judge Hall's portion of the Court's website, in the "Forms" tab, under the heading "Motion for Teleconference to Resolve Discovery/Protective Order Disputes." The dispute will thereafter be addressed in accordance with Judge Hall's discovery dispute procedures. ORDERED by Judge Jennifer L. Hall on 10/15/2020. (ceg)

**1:18-cv-00823-CFC-JLH Notice has been electronically mailed to:**

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**1:18-cv-00823-CFC-JLH Filer will deliver document by other means to:**

Matt Lembo

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# **EXHIBIT 22**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR	)	
STERILE PRODUCTS, LLC, and ENDO	)	
PAR INNOVATION COMPANY, LLC,	)	
	)	
Plaintiffs,	)	C.A. No. 18-823-CFC
	)	
v.	)	
	)	
EAGLE PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	

**EAGLE PHARMACEUTICALS INC.’S FIRST SET OF REQUESTS FOR  
PRODUCTION (NOS. 1-81) TO PAR PHARMACEUTICAL**

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Defendant Eagle Pharmaceuticals Inc. (“Eagle” or “Defendant”), by and through its attorney, requests that Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (“Par” or “Plaintiffs”) produce the documents and things requested herein at the offices of Kirkland & Ellis LLP, 601 Lexington Avenue, New York, New York 10022, or at such other location to which the parties mutually agree, and provide written responses to these requests within thirty (30) days of service of these requests.

**DEFINITIONS**

The terms listed below have the following meanings:

1. “Par,” “Plaintiffs,” “You,” or “Your” means Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC collectively, and all present and former parents, subsidiaries, and affiliates thereof, all divisions, predecessors, successors, and assigns thereof, and all directors, officers, employees, agents, consultants, representatives, or persons acting or purporting to act on behalf of, or under the control of, any of the foregoing entities; and all other Persons, acting or purporting to act under Plaintiffs’ control or on Plaintiffs’ behalf, and/or

**REQUEST NO. 32:**

All documents and things concerning any publication, patent, patent application, or prior art concerning vasopressin.

**REQUEST NO. 33:**

All documents and things on which Plaintiffs intend to rely to support any contention that any composition or formulation of vasopressin has unexpected or superior properties to any other compound, composition or formulation.

**REQUEST NO. 34:**

All documents sufficient to show the sales of Vasopressin® brand vasopressin in dollars and in units for each year in which it has been sold.

**REQUEST NO. 35:**

All documents and things concerning any comparison including, but not limited to, comparative tests or experiments, between any composition or formulation of vasopressin and any other compound, composition or formulation, including but not limited to any other composition or formulation of vasopressin.

**REQUEST NO. 36:**

All documents and things concerning any report, memorandum, meeting minutes, meeting summaries, or publications relating in any way to research leading to vasopressin or its formulation into a pharmaceutical dosage form.

**REQUEST NO. 37:**

All documents and things concerning the license, sale, or assignment of any rights to any vasopressin composition or formulation(s).

**REQUEST NO. 38:**

All documents and things concerning any license, transfer, or assignment of rights to any of the '239 patent, the '233 patent, the '478 patent, the '526 patent, the '785 patent, and the '209 patent.

**REQUEST NO. 39:**

All documents sufficient to show the total amount spent on promotion and marketing of Vasopressin® in each year in which it has been sold.

**REQUEST NO. 40:**

All documents and things concerning any strategic plans, business plans, marketing plans, brand plans, competitive evaluations, market research, market analyses, advertising plans,

**REQUEST NO. 62:**

All documents and things concerning the level of ordinary skill in the art for any claim of the Patents-in-Suit.

**REQUEST NO. 63:**

All documents, communications, and things, including, without limitation, laboratory notebooks, reports, memoranda, protocols, and data, concerning the subject matter of any declaration or affidavit submitted to the United States Patent & Trademark Office during prosecution of the Patents-in-Suit, any related patent or patent applications, any other Plaintiffs' patents relating to vasopressin, or their Foreign Counterparts, including but not limited to the materials, information, data, or documents considered during preparation of any such declaration or affidavit, any analysis undertaken during preparation of any such declaration or affidavit, the selection of any materials, information, data, or documents for submission with any such declaration or affidavit, the omission of any materials, information, data, or documents from any declaration or affidavit, the statements or content of any such declaration or affidavit, and the basis for the statements or content of any declaration or affidavit.

**REQUEST NO. 64:**

All documents, communications, and things regarding any vasopressin product marketed prior to the first FDA approval of NDA No. 204485.

**REQUEST NO. 65:**

All documents, communications, and things, including, without limitation, laboratory notebooks, reports, memoranda, protocols, and data, regarding any comparison between any vasopressin product marketed prior to the first FDA approval of NDA No. 204485 and any other vasopressin formulation, including, but not limited to, Vasostrict® and the subject matter of the Patents-in-Suit.

**REQUEST NO. 66:**

All documents, communications, and things, including, without limitation, laboratory notebooks, reports, memoranda, protocols, and data, regarding any stability testing of any vasopressin formulation, including, but not limited to, Vasostrict®, the subject matter of the Patents-in-Suit, and any vasopressin formulation marketed prior to the first FDA approval of NDA No. 204485.

**REQUEST NO. 67:**

All financial and sales projections for Vasostrict®.

**REQUEST NO. 68:**

All documents sufficient to show the net profit earned from the sale of Vasostrict®.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

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Dated: November 2, 2018  
5990659 / 45185

By: /s/ Jennifer Penberthy Buckley  
David E. Moore (#3983)  
Bindu A. Palapura (#5370)  
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*Attorneys for Defendant Eagle  
Pharmaceuticals Inc.*

# EXHIBIT F

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., )  
PAR STERILE PRODUCTS, LLC, and )  
ENDO PAR INNOVATION )  
COMPANY, LLC, )

Plaintiffs,

V.

EAGLE PHARMACEUTICALS INC., )  
 )  
Defendant. )

C.A. No. 18-823-CFC-JLH

**LETTER TO THE HONORABLE COLM F. CONNOLLY**  
**BINDU A. PALAPURA, ESQUIRE**

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Dated: October 28, 2020  
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October 28, 2020

**VIA ELECTRONIC FILING**

The Honorable Colm F. Connolly  
United States District Judge  
J. Caleb Boggs Federal Building  
844 N. King Street  
Wilmington, DE 19801

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC-JLH

Dear Judge Connolly:

I write on behalf of Eagle Pharmaceuticals in response to Par's October 26 letter submitted in advance of today's Status Conference (D.I. 210). Eagle proposed that the parties request a status conference in order to apprise the Court of the current landscape, including the possibility of a launch-at-risk scenario and/or injunctive relief that Par might seek. The parties had discussed possible joint proposals for how we could proceed, but did not reach agreement.

The salient issue before the Court is when to schedule trial and/or preliminary injunction proceedings, so that the Court and parties can proceed in an orderly fashion now that the 30-month stay of final approval of Eagle's ANDA has expired.

Since FDA has granted Eagle's ANDA "priority review" FDA could approve at any time, even before the end of this year. Eagle has invested heavily in the development of this product, which is important to Eagle's business.

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That means these issues could come to a head at any time. Eagle thus believes it is in the interests of the Court and parties to schedule trial, and/or prepare for and schedule proceedings for injunctive relief, sooner rather than later, if possible. Otherwise, the parties may come to the Court on an even more urgent or emergency basis, which could be particularly unideal given the complexities of the Court's schedule due to the pandemic. [REDACTED]

[REDACTED] having had injunction proceedings or a trial already would provide more certainty and [REDACTED]. Indeed, one goal of the Hatch-Waxman framework is to get to trial and decision before a launch, which is why litigation runs in parallel to FDA proceedings and trials often occur before tentative approval.

As for the merits of Par's assertion [REDACTED]

[REDACTED] (D.I. 210), it misses the mark. Par correctly acknowledges—as it has to—that FDA has granted “priority review” to Eagle’s ANDA. Par Ex. I. Par states that priority review [REDACTED]

[REDACTED] D.I 210, Attachment at 2. [REDACTED]

Under FDA’s Manual of Policy and Procedures, an ANDA granted priority review may receive *either* a shorter goal date (*if* the submission has not yet been assigned a goal date), *or* expedited review. FDA MaPP 5240.3 Rev. 5 at 3. Here, [REDACTED]

[REDACTED] Par Ex. I.

Par’s argument that [REDACTED]” (D.I. 210), is wholly speculative. [REDACTED]. Likewise, [REDACTED] (D.I. 210, Attachment at 2), deserves no serious consideration. Eagle [REDACTED]

[REDACTED] Par Ex. G at 6–7. [REDACTED]

And in any event, since even Par acknowledges [REDACTED] scheduling trial and/or injunction proceedings now would allow for an orderly trial or hearing, and briefing, before Eagle’s launch, much like the time between the original May 2020 trial date and the October 2020 expiry of the 30-month stay, which was set for that very reason.

We look forward to discussing these issues during the upcoming Status Conference.

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Respectfully,

*/s/ Bindu A. Palapura*

Bindu A. Palapura

BAP:nmt/6915254/45185

cc: Counsel of Record (via electronic mail)